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David M. Hardin JR.

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EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/731,500	<b>Applicant(s)</b> HARDIN ET AL.	
	<b>Examiner</b> HELEN NGUYEN	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75 and 80-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75 and 80-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/6/2007</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is responsive to the amendment filed 12/6/2007. Claims 1-2, 16, 53-54, 70, and 72 are amended. Claims 15, 25, 69, and 79 are cancelled, rendering the previous drawing objections moot. **Claims 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75, and 80-83** remain pending and under prosecution.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 12/6/2007 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75, and 80-83** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the specification does not appear to disclose the needle comprising a flexible shaft. Indeed, as the shaft is disclosed as made of steel or a metal, it is unclear how much flexibility is afforded to the needle by the recitation in the claims of a flexible shaft.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-2, 7, 9-11, 20, and 29** are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Reeves et al (US Pat No. 7056293).

7. In regards to **Claim 1**, Reeves et al disclose a medical apparatus comprising:

a needle 12 comprising an elongate flexible shaft having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end, best seen in Figure 3, the shaft being capable of and thus adapted to extend through a working channel of an endoscope;

a stylet 16 having a proximal end and a distal end, wherein said stylet is adapted to be inserted into and withdrawn from said inner lumen of said needle with at least a portion of said stylet adapted to plug said inner lumen of said needle when a cytology sample is cut (Col.3: 27-35);

a cytology collection device 48 having a proximal end and a distal end, wherein said cytology collection device is adapted to be inserted into said inner lumen of said needle when said stylet is withdrawn from the inner lumen of said needle, with said distal

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end of said cytology collection device adapted to extend beyond the distal end of said needle in order to collect said cytology sample, best seen in Figure 2 (Col.4: 45-55).

8. In regards to **Claims 2**, Reeves et al disclose said cytology collection device 48 comprises an elongate member having a proximal end, a distal end, and a plurality of bristles (Col.4: 22-28), the distal end being adapted to plug said inner lumen of said needle after the cytology sample has been collected.

9. In regards to **Claim 7**, Reeves et al disclose the distal end of the elongate member is adapted to be retracted within the inner lumen of said needle after collecting said cytology sample.

10. In regards to **Claim 9**, Reeves et al disclose said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer (Col.4: 25-27).

11. In regards to **Claim 10**, Reeves et al disclose said needle 12 is capable and thus adapted to provide suction.

12. In regards to **Claim 11**, Reeves et al disclose a handle 20 which is adapted to provide axial movement of said cytology collection device 48 and said needle 12, best seen in Figure 3.

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13. In regards to **Claim 20**, Reeves et al disclose said stylet 16 is a solid rod used to plug said needle.

14. In regards to **Claim 29**, Reeves et al disclose an outer surface of said stylet 16 has a first diameter and an inner surface of said needle 12 has a second diameter slightly larger than said first diameter, wherein said outer surface of said stylet is adapted to contact said inner surface of said needle to plug said inner lumen of said needle while said cytology sample is cut (Col.3: 31-34).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claims 3-6, 8, 21, 26-28, 53-62, 74-75, and 80-83** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Wang (US Pat No. 4966162).

17. In regard to **Claims 3-6**, Reeves et al disclose the cytology collection device 48 above but do not explicitly disclose the structure and material of its distal end or the structure and material of its elongate member. Wang discloses an analogous cytology collection device 176, 230 having a distal end terminating in a loop 232 and comprises a wire 170 twisted around a plurality of bristles 178, best seen in Figures 6 and 11. Wang also discloses said cytology collection device made of steel (Col.6: 10-24). Therefore, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to make the cytology collection device of Reeves et al to have a distal end terminating a loop and also comprising a wire twisted around a plurality of bristles and said distal end and said wire made of steel as taught by Wang as an effective configuration and make of said cytology collection device for the purpose of sampling.

18. In regard to **Claims 8 and 21**, Reeves et al disclose the needle 12 and stylet 16 above but do not specify the material. Wang discloses an analogous device made of steel (Col.8: 35-36) as an effective material used for tissue sampling. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the needle and style of Reeves et al out of steel as taught by Wang as a desirable material used for such sampling device.

19. In regard to **Claims 26-27**, Reeves et al disclose the stylet 16 above but do not disclose said style adapted to cut said cytology sample. Wang teaches an analogous style 140 having a sharp distal end 174, best seen in Figure 3 and 6 to cut a cytology sample allowing greater range of sampling (Col.6: 47-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the stylet of Reeves et al with a sharp distal end adapted to cut a cytology sample as taught by Wang to allow penetration of cysts and other tissue for a greater sampling range.

20. In regards to **Claim 28**, Reeves et al in combination with Wang disclose said distal end of said stylet 16 is adapted to extend beyond the distal end of said needle 12.

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21. In regard to **Claims 53 and 80-82**, Reeves et al disclose a method for collecting a cytology sample from a mammalian body comprising:

providing an apparatus comprising: a needle 12 comprising an elongate flexible shaft having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end, the shaft being capable of and thus adapted to extend through a working channel of an endoscope; a stylet 16 having a proximal end and a distal end; a cytology collection device 48 having a proximal end and a distal end for cytology collection;

inserting said stylet into said inner lumen of said needle, wherein at least a portion of said stylet plugs said inner lumen of said needle (Col.3: 31-34);

withdrawing said stylet from said inner lumen of said needle (Col. 4: 45-47);

inserting said cytology collection device into said inner lumen of said needle so that said distal end of said cytology collection device extends beyond the distal end of said needle (Col.4: 54-55);

collecting said cytology sample from said mammalian body using said cytology collection device (Col.4: 55);

retracting said distal end of said cytology collection device into said inner lumen of said needle, wherein at least a portion of the distal end of the cytology collection device plugs said inner lumen of said needle (Col.56-60).

22. However, Reeves et al do not disclose the method step of cutting an area within said mammalian body with said stylet. Wang teaches an analogous collection method including the step of cutting tissue to gain greater access into tissue for sampling (Col.2: 6-16). Therefore, it would have been obvious to one of ordinary skill in the art at the



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time the invention was made to modify the method of Reeves et al to include the step of cutting an area within said mammalian body such as with the sharpened stylet to gain greater access to tissue for sampling.

23. In regard to **Claims 54, 60, 62, 74, and 83**, Reeves et al in combination with Wang disclose the claimed elements in the manner previously explained in the above rejections of Claims 2, 9, 11, 20, and 29 respectively.

24. In regard to **Claims 55-58**, Reeves et al in combination with Wang disclose the claimed elements in the manner previously explained in the above rejections of Claims 3-6 respectively.

25. In regard to **Claims 59 and 75**, Reeves et al in combination with Wang disclose the claimed elements in the manner previously explained in the above rejections of Claims 8 and 21 respectively.

26. In regards to **Claim 61**, Reeves in combination with Wang disclose the method above but do not disclose the step of providing suction through said needle. Wang teaches that suction is advantageously used to effectively sample tissue during use (Col.4: 4-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Reeves as modified by Wang to include the step of providing suction through the needle to enhance the sampling process.

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27. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Rabiner et al (US Pat No. 6579279).

28. Reeves et al disclose the handle 20 above but do not disclose said handle comprising an inner handle member, a first outer handle member, and an elongate sheath. Rabiner et al disclose an analogous device comprising an inner handle member 40 having a proximal end and a distal end; a first outer handle member 42 slideably disposed on the inner handle member; and an elongate sheath 26 attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen to allow a catheter 29 to be disposed in the sheath lumen, best seen in Figures 1-2. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the handle of Reeves et al to include an inner handle member, a first outer handle member, and an elongate sheath in the manner taught by Rabiner et al an effective arrangement that allows locking and relative movement and rotation of said handle members as well as the component disposed within the sheath, wherein in use it would be obvious to place the needle within the sheath lumen.

29. **Claims 16 and 18-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Ishiguro (US Pat No. 6108439).

30. In regards to **Claim 16**, Reeves et al disclose the device above including an endoscope and a means for imaging the position of the cytology collection device but do not disclose the use of an ultrasound transducer to determine the position. Ishiguro teaches an ultrasound transducer 10 that emits ultrasound waves used to determine

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position (Col.11: 61-67; Col.12: 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the imaging means of Reeves with the ultrasound transducer of Ishiguro as an equally as effective means to determine the position of said cytology collection device within the body, wherein the needle and the cytology collection device area capable of being disposed simultaneously through a working channel of the endoscope.

31. In regards to **Claim 18**, Reeves et al in combination with Ishiguro disclose said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said plurality of bristles.

32. In regards to **Claim 19**, Reeves et al disclose said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer (Col.4; 25-27).

33. **Claims 63** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view of Wang, further in view of Rabiner et al in the manner previously explained in the above rejection of Claim 12.

34. **Claims 70 and 72-73** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al in view Wang, further in view of Ishiguro in the manner previously explained in the above rejections of Claims 16 and 18-19.

***Response to Arguments***

35. Applicant's arguments filed 12/6/2007 have been fully considered but they are not persuasive. Applicant contends that Reeves et al do not disclose a needle comprising an elongate flexible shaft. However, as evidenced by the §112 1<sup>st</sup> rejection above, there does not appear to be a disclosure of the needle being flexible in the specification. Furthermore, as the needle of Reeves et al is likely made of steel or metal just like Applicant's own needle (and it is also obvious to do so as explained in the above rejection), it is believed that the needle of Reeves et al would likewise provide the same manner of flexibility. Additionally, all materials contain at least some degree of flexibility, and it is noted that Applicant has failed to both describe in the specification and recite in the claims the nature of this flexibility. Thus, it is maintained that Reeves et al disclose the needle comprising an elongate flexible shaft as claimed.

36. Applicant also contends that Reeves et al do not disclose the needle adapted to extend through a working channel of an endoscope and actually teaches away from that. However, it is noted that due to the at least the size and shape of the needle, said needle is capable of extending at least some extent into the working channel of an endoscope. It is also noted that just because Reeves et al disclose a fiber optic device inserted into the needle does not also preclude use of extending the needle through an endoscope. Therefore, it is respectfully maintained that not only is there no teaching away, Reeves et al do indeed disclose said needle adapted to extend through a working channel of an endoscope as claimed. It is also noted that the current recitation of the needle adapted to extend through the endoscope does not constitute a positive recitation, for example, the endoscope is not really a claimed structure in the apparatus. A recitation of the intended

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use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

### ***Conclusion***

37. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736